Remarks

Please amend claim 76 and cancel claims 1-2, 15-16, 21, 34, 36-74 and 77-134. Following this amendment claims 3-4, 13-14, 17, 20, 22-23, 75, 76 and 135-194 will be pending of which claims 3-4, 13-14, 17, 20, 22-23 are withdrawn. Each of the new claims are directed to Zidovudine as the active agent. Support for the claims as amended may be found for instance on page 3, lines 17-20, page 4, lines 6-17, page 7, lines 12-19, in the Examples, such as Example 13 and throughout the application as originally filed. No new matter is added as a result of this amendment. Applicants believe the current amended claims and remarks below address the Examiner's remaining concerns.

With regard to the Cross Referenced Applications, Applicants filed an Amendment and Petition on June 17, 2004, for unintentional delay to correct the errors with regard to priority and to amend the specification accordingly.

Objections

Applicants appreciate the Examiners comments with regard to claim Claim 76 and have amended the claim pursuant to the Examiner's suggestions. Withdrawal of the objection is respectfully requested.

Rejection Under 35 U.S.C. § 112 ¶2

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Applicants appreciate the Examiners comments with regard to claim Claim 76 and have deleted the phrase "BCX CW1812" from the claim. Withdrawal of the rejection is respectfully requested.

35 U.S.C. §102(b)

> A person shall be entitled to a patent unless -
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in a public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 75 and 76 were rejected under 35 U.S.C. §102(b) as anticipated by several references which are addressed individually below. "Anticipation under 35 U.S.C. § 102 requires the disclosure in a single piece of prior art of each and every limitation of a claimed invention." (*Electro Med. Sys. S.A. v. Cooper Life Sciences*, 32 U.S.P.Q.2d 1017, 1019 (Fed. Cir. 1994)). The amended claims, through restriction, are directed to zidovudine which is covalently attached through its hydroxyl group to a carboxyl group or an amine group of select amino acids. The claims as amended make it clear that zidovudine is not in a phosphorylated form as the covalent attachment is occurring through the hydroxyl group of the zidovudine. Additionally, several of the claims are directed to the composition in a form suitable for oral delivery and enzymatic release into the bloodstream following oral delivery. It is respectfully submitted that the claims as amended address the Examiner's concerns regarding each of the references as further discussed below.

Claims 75 and 76 were rejected under 35 U.S.C. §102(b) as anticipated by Lazo et al. (WO 98/04277) which purportedly teaches therapeutic agents including zidovudine "attached via its amine group to the C-terminus of a peptide having eleven amino acids. The claimed invention is not attached through zidovudine's amine group. The rejection is respectfully mooted.

Claims 75 and 76 were rejected under 35 U.S.C. §102(b) as anticipated by Lee et al. (U.S. Patent 5,534,496) which purportedly teaches drugs which are antiviral agents. As the claimed invention, through both election and amendment, is directed to zidovudine and not additional anti-virals. The rejection is respectfully traversed. In the event the examiner wishes to maintain the rejection applicants respectfully request the Examiner remove the election of species and allow applicants to pursue the full breadth of anti-virals in one case.

Claims 75 and 76 were rejected under 35 U.S.C. §102(b) as anticipated by Fiume et al. (U.S. Patent 5,594,110) which purportedly teaches "AZT covalently conjugated to lactosaminated human albumin." Fuime et al. utilize a phosphorylated form of AZT to attach an imidazolide to the AZT which is then utilized to attach human albumin. The claimed invention is neither phosphorylated or attached through an imidazolide. The rejection is respectfully traversed.

Claims 75 and 76 were rejected under 35 U.S.C. §102(b) as anticipated by Yatvin et al. (U.S. Patent 5,965,519) which purportedly teaches "AZT covalently conjugated through a phosphate group to tetraglycine." Yatvin et al. utilize a phosphorylated form of AZT. The claimed invention is directed to AZT not a mono-phosphorylated form of AZT. The rejection is respectfully traversed.

Claims 75 and 76 were rejected under 35 U.S.C. §102(b) as anticipated by Simon et al. (U.S. Patent 5,965,695) which purportedly teaches "AZT covalently bound to a peptoid comprising 2 to 50 N-substituted glycine residues." Simon et al. does not disclose AZT covalently attached through a hydroxyl group to only naturally occurring amino acids. The rejection is respectfully traversed.

Claim 75 was rejected under 35 U.S.C. §102(b) as anticipated by Josephson et al. (U.S. patent 5,981,507) which purportedly teaches "araA conjugated to polyglutamic acid." Similar to Fuime and Yatvin, Josephson utilizes amino-phosphate linkages to attach their active agents. As the claimed invention is directed to covalent attachment of AZT through its hydroxyl and not a phophorylated form of AZT, the rejection is respectfully traversed.

Claims 75 and 76 were rejected under 35 U.S.C. §102(b) as anticipated by Japanese Patent Application Publication 2-59526 which purportedly teaches "AZT covalently conjugated to polypeptides such as antibodies, albumin, transferrin, lysozyme, fibrin, actin, myosin, poly-lysine, and poly-L-glutamic acid." Applicants contend that the abstract is an insufficient reference. Applicants request the Examiner provide a full translation of the document from which the abstract is taken from if the Examiner wishes to use the reference. The Board recently held:

> [w]hen Applicants or their representatives cannot read the non-English language, however, they may not be able to form an adequate understanding of the reference to rebut the rejection on the merits or to amend the claims to avoid the reference. In such cases, Applicants should **insist that the examiner provide a translation** before a final rejection is entered, seeking supervisory intervention if necessary. (*Ex parte Bonfils*,

64 U.S.P.Q.2d 1456, 1461 (Bd. Pat. App & Interf. 2002)(Emphasis Added)(*See also infra, Ex parte Gavin*)(copies provided).

Additionally, the Board held:

> Generally an abstract does not provide enough information to permit an objective evaluation of the validity of what it describes. Thus, an abstract is even less reliable a basis to extrapolate the alleged teachings of the underlying document to different circumstances....**Citation of an abstract** without citation and reliance on the underlying scientific document itself is generally **inappropriate** where both the abstract and the underlying document are prior art. (*Ex parte Gavin*, 62 U.S.P.Q.2d 1680, 1684 (Bd. Pat. App & Interf. 2001)(Emphasis Added).

Applicants request the Examiner utilize his discretion under MPEP 905.01(d) to obtain a written translation of the underlying document if the rejection is maintained. It appears the reference is directed to an aldehyde derivative of AZT. However, in the absence of a translation, Applicants respectfully request the rejection be withdrawn.

Claims 75 and 76 were rejected under 35 U.S.C. §102(b) as anticipated by the Giammona et al. article which purportedly teaches "zidovudine covalently conjugated to polyaspartamide." As the claimed invention is directed to AZT directly attached to selected amino acids whereas Giammona is directed to AZT attached through a linker, succinyl, to PHEA. The rejection is respectfully traversed.

Claims 75 and 76 were rejected under 35 U.S.C. §102(b) as anticipated by the Hussain et al. article which purportedly teaches "AZT covalently conjugated to polypeptides comprised of lipidic amino acids." Hussain's amino acids have alkyl lengths from 9 to 17 carbon atoms. The claimed invention is directed to selected amino acids which do not have alkyl lengths from 9 to 17 carbon atoms. The rejection is respectfully traversed.

Claims 75 and 76 were rejected under 35 U.S.C. §102(b) as anticipated by the Matsumoto et al. article which purportedly teaches "AZT conjugated to a dipeptide comprising

two different non-natural amino acids." As the claimed invention comprises AZT covalently attached to a naturally occurring amino acid, the rejection is respectfully traversed.

CONCLUSION

No additional fees are believed to be necessary in connection with the filing of this paper. However, in the event any fees are necessary, the Commissioner is hereby authorized to charge Deposit Account 50-0206 for any such fees.

Respectfully submitted,

HUNTON & WILLIAMS LLP

By: _____
Jeffrey T. Perez
Registration No. 52,110

Hunton & Williams LLP
Intellectual Property Department
1900 K Street, N.W. Suite 1200
Washington, DC 20006-1109
(202) 955-1500 (telephone)
(202) 778-2201 (facsimile)

Dated: Aug 11, 2004